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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/759,908

01/16/2004

Thomas M. Burke

31545-1010 (PBD-1010)

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04/16/2008

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EXAMINER

SHAHRESTANI, NASIR

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/759,908 | Applicant(s) BURKE, THOMAS M. | |
| | Examiner NASIR SHAHRESTANI | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/16/2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-22 are pending.

No new claims have been added.

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 14-15, 17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills (U.S. Pub. No.: 2002/0188195).

Regarding claims 1-6, 14, 17, Mills teaches a medical device (see title) suitable for MRI (par.[0011]) comprising: a polymeric, tubular body component (fig. 1) configured for attaining a diagnostic or therapeutic goal (par.[0074]) using a working end (element 6); **and a microcapsule additive (radioisotope component 4)** being substantially free of gas inclusions, disposed within at least a portion of the polymeric component (fig. 5), comprising a fluid impermeable shell

Art Unit: 3737

coating component (par. [0092]) containing an MRI contrast enhancing fluid (par.[0014]). Said contrast enhancing fluid renders a portion of the polymeric component directly visible during imaging (par. [0021]). Mills further teaches wherein the spacer element or body chamber may further comprise a contrast material such as silver, gold, or tungsten (par. 0014).

Regarding claim 7, 15, 20, Mills further teaches wherein the contrast enhancing fluid exhibits a high density of free protons with relaxation properties (par. [0075]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (U.S. Pub. No.: 2002/0188195) in view of Cheng (U.S. Patent No.: 5,023,072).

Mills teaches all the limitations of claim 7 but does not teach wherein the contrast enhancing fluid comprises mineral oil, cod liver oil, terpene, or polyunsaturated fatty acids. Cheng teaches the use of mineral oil as a contrast enhancing fluid (col. 1 lines 52-68, col. 2 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of then invention to have modified the apparatus as taught by Mills and to have incorporated the use of Mineral Oil as taught Cheng in order to provided for optimized imaging by opacating bowel loops by increasing proton density during MRI.

Claims 10-13, 19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (U.S. Pub. No.: 2002/0188195) in view of Edwards et al. (U.S. Patent No.: 5,985,309).

Mills teaches all the limitations of claim 1 but does not teach wherein the microcapsule is formed by various methods of deposition, polymerization, etc. Edwards et al. teaches the

Art Unit: 3737

aforementioned limitations wherein polymeric particles for MRI may be prepared using various techniques such as coacervation and interfacial polymerization (col. 8 lines 7-19) and wherein the shell component is chemically compatible with the polymeric component (col. 6 lines 2-16). It would have been obvious to one of ordinary skill in the art at the time of then invention to have modified the apparatus as taught by Mills and to have incorporated the method of manufacture of polymers as taught by Edwards et al. to optimize conditions for forming microcapsules with a desired aerodynamic diameter.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (U.S. Pub. No.: 2002/0188195) in view of Osborne et al. (U.S. Patent No.: 6,623,722).

Mills teaches all the limitations of claim 7 but does not teach wherein the relaxing modifying agents are selected from the group consisting of iron oxide particles and anchored gadolinium based reducing agents. Osborne et al. teaches functional contrast agents selected from the group of iron oxide gadolinium (col. 2 lines 59-64). It would have been obvious to one of ordinary skill in the art at the time of then invention to have modified the apparatus as taught by Mills and to have used the agents as taught by Osborne et al. to provide for longer half-life of the contrast agent.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. S./

Examiner, Art Unit 3737

/Brian L Casler/

Supervisory Patent Examiner, Art Unit 3737